Standard Operating Procedure

SUBJECT: Develop and Manage a Case Report Form (CRF) under the caBIG™ Program	SOP No.: CR-003
	Version No.: 1.0
	Effective Date: 10/31/2005
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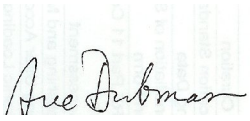
Standard Operating Procedure – Develop and Manage a Case Report Form

This cover sheet controls the layout and components of the entire document.

Issued Date: September 19, 2005

Effective Date: October 31, 2005

Department Approval:



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QA Approval:

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Note: This document will be issued for training on the Issue Date. The document will become available for use to trained personnel on the Effective Date. Before using this document, make sure it is the latest revision. Access the caBIG™ website to verify the current revision.

Revision History

Revision	Date	Author	Change Reference	Reason for Change
1.0	09/19/2005	SOP Working Group	N/A	Initial release.

1. Purpose

This Standard Operating Procedure (SOP) describes the process for the development and maintenance of Case Report Forms (CRFs) used in clinical research trials under the caBIG™ Program.

2. Scope

This SOP will be used for the development and maintenance of all CRFs for clinical trials research covered under the caBIG™ Program and sponsored by the National Cancer Institute (NCI).

3. Requirements

3.1 An approved, signed-off protocol needs to be in place and all data elements that support the objectives of the protocol need to be identified (e.g. primary and secondary endpoints for product efficacy and/or procedures, as well as all required patient safety information).

3.2 All clinical research data will be collected using case report forms (CRFs) that capture data as required by the protocol.

3.3 All staff responsible for filling the roles identified in the *Roles and Responsibility* section will receive training on this SOP.

3.4 The CRF physical layout must be reviewed and the content verified against the protocol before the CRF is approved and implemented.

4. References/Regulations/Guidelines

Section	Document Number	Title
4.1	N/A	CDISC Glossary
4.2	CR-001	SOP for Study Set Up
4.3	CR-004	SOP for CDE Curation
4.4	CR-005	SOP for Application's Standard Library Maintenance
4.5	N/A	ICH E6 Good Clinical Practice, "Records and Reports", Section 4.9

5. Roles & Responsibilities

Role	Responsibility
Project Lead (e.g., Protocol build team)	• Request CRF to be compiled to support protocol execution. • Amend physical layout of CRF. • Compile list of changes to physical layout of CRF after review.
Study Designer	• Review CRF request and creates electronic version of the CRF. • Compile/manage the electronic representation of the CRF throughout the lifecycle.
Review Team (e.g., clinical research team, PI, RN, statistician)	• Review content of the draft CRF against the protocol requirements and provides comments. • Review printed physical layout of CRF and provides comments. • Sign off version of final printed CRF.
CRF Oversight Officer/Committee	• Approve decision on CRF changes and new CRF development. • Sign off on final CRF change requests.

6. Attachments

This SOP will be used in conjunction with the following attachments. These attachments must be used by all research sites conducting clinical trials under the caBIG™ Program and can be customized by individual research sites to accommodate format and content in accordance with local guidelines and/or requirements.

Title	Description
1) Procedure Description for Develop and Manage a CRF	This document provides instructions for the development and management of a Case Report Form (CRF). It provides step-by-step guidance to ensure that all CRFs are developed and managed in a consistent manner.
2) CRF Questionnaire	This questionnaire can be used to map protocol required data to the CRF.
2) Process Flow for Develop and Manage a CRF	This document identifies the workflow activities, by role, for the steps identified in the Procedure for Developing and Managing a CRF.